

3rd International Conference and Exhibition on **Biowaivers, Biologics & Biosimilars**

October 27-29, 2014 Hyderabad International Convention Centre, Hyderabad, India

Preparing for U.S. market entry—strategy considerations in view of BPCIA and AIA

Renita S Rathinam
Sughrue Mion PLLC, USA

With clarity concerning the Biologics Price Competition & Innovation Act (BPCIA) of 2010 and imminent significant patent expirations on the horizon, the U.S. biologics market remains an increasingly prized landscape for industry players. We will revisit the BPCIA litigation framework and also examine critical paradigm shifts in U.S. patent law via the America Invents Act of 2011 that cannot be overlooked by biosimilar applicants or reference product sponsors. We will examine how these two pieces of legislation together present unique considerations for prosecution, collaboration and litigation strategies that should be implemented now.

rrathinam@sughrue.com